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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,879	01/18/2002	Jonathan S. Till	10551/317	8705

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WASHINGTON, DC 20005

EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/12/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/050,879

Applicant(s)

TILL, JONATHAN S.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,8,11-24,26,31 and 33 is/are rejected.
- 7) ☒ Claim(s) 4-6,9,10,25,27-30 and 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Receipt is acknowledged of the preliminary amendment filed 04/03/02.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claim for "preventing" presbyopia or formation of disulfide bonds

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides for a method of treating presbyopia and increasing the amplitude of accommodation of a human eye by administering a compound which breaks disulfide bonds along with some form of applied energy.

(2) The state of the prior art

The prior art contains references which use compounds such as glutathione or energy separately as a treatment of presbyopia.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

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(4) The predictability or unpredictability of the art

The unpredictability of the art is very high. While treatment of presbyopia is art recognized, there is nothing in the art which would lead one in the art to reliably predict prevention of presbyopia without undue experimentation on those who have been given the treatment, and for an undetermined period of time.

(5) The breadth of the claims

The claims are directed to a treatment method and composition comprising administration of an energy source and a compound which breaks disulfide bonds.

(6) The amount of direction or guidance presented

The specification does not contain any guidance or support for the "prevention of presbyopia". Indeed, this would necessitate undue experimentation on each subject in order to provide support for this assertion. The specification should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F.2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F.2d 349, 151 USPQ 724.

(7) The presence or absence of working examples

No working examples are provided.

(8) The quantity of experimentation necessary

Since the "prevention of presbyopia or formation of disulfide bonds" would require screening of each individual tested for an undetermined period of time, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine whether all of those given the treatment would be prevented from developing presbyopia at some undetermined point in the future.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 11, 17, 22-24, 26, 31 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hofmann et al.

Hofmann et al disclose an eye drop composition which improves lens pliability (see Abstract). Reduction of the pliability (or presbyopia) is reversed by the method and composition of Hofmann et al (see col. 1, lines 17-18; col. 2, lines 9-12). The crosslinking of collagen fibers by deposition of heavy metals (interlenticular fiber

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adhesions) is recognized as a cause of lens hardening (see col. 1, lines 21-38). The composition comprises a glutathione, preferably as L-Glutathione and in an amount between about 0.1 to 0.5% (see col. 1, lines 44-46; col. 2, lines 24-30). A biocompatible carrier is described at col. 3, lines 33-40. The instant claims are clearly anticipated by Hoffman et al.

Claims 4-6, 9, 10, 25, 27-30, and 32 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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August 8, 2003



CARLOS AZPURU  
PRIMARY EXAMINER  
GROUP 1500